IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	:	10/753,669
Inventor(s)	:	Donald C. Roe et al.
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Art Unit	:	3761
Examiner	:	Jacqueline F. Stephens
Docket No.	:	7537CQ
Confirmation No.	:	1141
Customer No.	:	27752
Title	:	Disposable Article Having A Biosensor

APPEAL BRIEF

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Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

This Brief is filed pursuant to the appeal from the decision communicated in the Final Office Action mailed on July 8, 2010.

A timely Notice of Appeal was filed on October 8, 2010.

REAL PARTY IN INTEREST

The real party in interest is The Procter & Gamble Company of Cincinnati, Ohio.

RELATED APPEALS AND INTERFERENCES

Applicant is unaware of any related appeals or interferences.

STATUS OF CLAIMS

Claims 1, 3-7, 9-11, 15-41, 43-45 and 47-52 are pending in the present application.

Claims 2, 8, 12-14, 42 and 46 were previously canceled without prejudice.

Claims 1, 3-7, 9-11, 15-41, 43-45 and 47-52 stand rejected and the rejections are the subject of the instant appeal.

STATUS OF AMENDMENTS

No claim amendments have been filed following the final rejection from which the instant appeal is taken. The claims were last amended by Applicants in a response dated July 1, 2010 and it is believed that all amendments have been entered.

SUMMARY OF CLAIMED SUBJECT MATTER

The application has two independent claims, Claims 1 and 40.

The subject matter of Claim 1 concerns a disposable article such as a diaper (20) to be fitted to a wearer comprising: a biosensor (60) including at least one biologically reactive bio-recognition element comprising a biologically derived material and adapted to detect or interact selectively with a specific microorganism selected from the group consisting of pathogenic bacteria, colonic bacteria, viruses, parasites and fungi, present in bodily waste or on the wearer's skin, the biosensor also being adapted to provide a signal of detection of the specific microorganism.

The subject matter of Claim 40 concerns a disposable absorbent article such as a diaper (20) to be fitted to a wearer comprising: a topsheet (24); a backsheet (26) joined with the topsheet; an absorbent core (28) disposed between the topsheet and the backsheet; and a biosensor (60) disposed on the disposable article, the biosensor

including at least one biologically reactive bio-recognition element comprising a biologically derived material and adapted to detect or interact selectively with a specific microorganism selected from the group consisting of pathogenic bacteria, colonic bacteria, viruses, parasites and fungi, present in bodily waste, the biosensor also being adapted to provide a signal of detection of the specific microorganism.

The dependent claims contain additional elements further characterizing the biosensor recited in Claims 1 and 40, in various ways.

(*See* Specification at page 3, lines 19-31; and page 12, line 20 through page 18, line 5; and Fig. 1.)

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Rejection of Claims 1, 3-7, 9-11, 15-19, 21-25, 36-39, 40, 41, 43-45, and 47-52 under 35 U.S.C. §103(a) as obvious over Everhart et al. (U.S. Pat. No. 5,468,236). (Office Action (7/8/10), ¶4.)

2. Rejection of Claims 28-35 under 35 U.S.C. §103(a) as obvious over Everhart et al. (U.S. Pat. No. 5,468,236) in view of Al-Sabah (U.S. Pat. No. 5,868,723). (Office Action (7/8/10), ¶6.)

ARGUMENT

A. Evidentiary Requirements for *Prima Facie* Conclusion of Obviousness – Prior Art Must Teach or Suggest All Claim Elements

Under MPEP §2142, the Office bears the burden of factually supporting an asserted *prima facie* conclusion of obviousness. In determining the differences between the cited art and the claims, the question is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. *See, e.g., Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1537; 218 U.S.P.Q. 871 (Fed. Cir. 1983). If the Office does not demonstrate *prima facie* unpatentability, then without more, the Applicant is entitled to the grant of the patent. *See In re Oetiker*, 977 F.2d 1443, 1445; 24 U.S.P.Q.2d 1443 (Fed. Cir. 1992).

To establish a *prima facie* case of obviousness under 35 U.S.C. §103, the Office must show that all of the claim elements are taught or suggested in the prior art. *See, e.g., CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1342; 68 U.S.P.Q.2d 1940 (Fed. Cir. 2003).

B. Discussion of Rejections

1. Everhart et al.

At Paragraph 4 of the Office Action, Claims 1, 3-7, 9-11, 15-19, 21-25, 36-39, 40, 41, 43-45, and 47-52 stand rejected under 35 U.S.C. §103(a) as obvious over Everhart et al. (U.S. Pat. No. 5,468,236). Applicant respectfully requests reversal of the rejection.

a. Independent Claims

Independent Claims 1 and 40, each recite a disposable article comprising a biosensor including at least one biologically reactive bio-recognition element comprising a biologically derived material and adapted to detect or interact selectively with a specific microorganism selected from the group consisting of pathogenic bacteria, colonic bacteria, viruses, parasites and fungi, present in bodily waste or on the wearer's skin, the

biosensor also being adapted to provide a signal of detection of the specific microorganism.

Everhart et al. does not teach or suggest such a biosensor, and particularly, one having a biologically reactive bio-recognition element that is adapted to detect or interact (1) *selectively* with (2) a *specific microorganism*, (3) *selected from the recited Markush group*.

The Office cites passages of Everhart et al. and alleges that these passages teach a "visual signal of detection of a specific microorganism." Applicants respectfully submit that the Office has ignored the claim term "selectively," has ignored the term "microorganism" or interpreted it unreasonably broadly, and has ignored the Markush group recited in Applicants' independent claims.

Careful review of the passages cited by the Office shows that all that Everhart et al. teaches is a "chemically reactive means" that may be capable of detecting the presence of one or more or more "substances" that may be present as a result of a "pathological disorder". (*See* Everhart et al. at col. 2, lines 57-06; col. 3, lines 10-30.) The Office has provided no interpretation of Applicants' claim terms, nor explained how Everhart contains teachings that fall within them.

First, the Office has not explained how it contends Everhart et al. teaches a biosensor that is adapted to detect or interact *selectively* with a specific microorganism. Applicants respectfully submit that Everhart et al. does not teach a biosensor that detects or interacts *selectively* with a specific microorganism.

Second, the Office has not explained how it contends Everhart et al. teaches a biosensor that is adapted to detect or interact selectively with a *specific microorganism*. Applicants respectfully submit that Everhart et al. does not teach that a "substance" its device can detect includes a *specific microorganism*. The term *microorganism* has the

following dictionary definition: "an organism of microscopic or ultramicroscopic size – used esp. of bacteria and protozoa . . . ." (Webster's Third New International Dictionary of the English Language Unabridged (1993) at 1428.) In turn, the term *organism* is defined in appropriate context: "an individual constituted to carry on the activities of life by means of parts or organs more or less separate in function but mutually dependent: a living being." (*Id.* at 1590.) Applicants respectfully submit that Everhart et al. does not teach that its "chemically reactive means" is adapted to detect a *specific microorganism* according to the ordinary meaning of that term. Rather, Everhart et al. only mentions detection by its "chemically reactive means" of various "substances" such as chemicals or leukocytes that may indicate a pathology. (Everhart et al. at col. 3, lines 10-30 and 48-65.)

Third, the Office has not explained how it contends Everhart et al. teaches a biosensor that is adapted to detect or interact selectively with a specific microorganism *selected from the group consisting of pathogenic bacteria, colonic bacteria, viruses, parasites and fungi*. Applicants respectfully submit that Everhart et al. does not teach that its "chemically reactive means" is adapted to detect a specific microorganism selected from this Markush group.

Thus, the Office has not established that the prior art teaches or suggests all of the elements of Applicants' independent Claims 1 and 40. For this reason, it has not established a *prima facie* case of obviousness. Applicants, therefore, respectfully request that the rejection of Claims 1, 3-7, 9-11, 15-19, 21-25, 36-39, 40, 41, 43-45, and 47-52 under 35 U.S.C. §103(a) based on Everhart et al. be reversed.

b. Particular Dependent Claims

In addition to the elements in independent Claims 1 and 40 discussed above, Claims 3, 4, 6 and 9 (dependent on Claim 1) and Claims 43, 44 and 47 (dependent on Claim 40) contain elements that further characterize the recited biosensor.

The Office has provided no analysis or explanation as to how it contends Everhart et al. teaches or suggests such additional elements. Applicants respectfully submit that Everhart et al. contains no such teaching. Applicants, therefore respectfully request that the rejection of Claims 3, 4, 6, 9, 43, 44 and 47 under 35 U.S.C. §103(a) based on Everhart et al. be reversed.

2. ***Everhart et al. in view of Al Sabah***

At Paragraph 6 of the Office Action, Claims 28-35 stand rejected under 35 U.S.C. §103(a) over Everhart et al. (U.S. Pat. No. 5,468,236) in view of Al-Sabah (U.S. Pat. No. 5,868,723).

As discussed above, Applicants submit that Everhart et al. does not teach or suggest all elements of Applicants' independent claims. As best understood by Applicants, Al-Sabah does not teach or suggest the claim elements missing from Everhart et al. For this reason, the combination of Everhart et al. and Al-Sabah does not support a *prima facie* conclusion of obviousness of the claims. For this reason, Applicants respectfully request reconsideration and withdrawal of the rejection.

CONCLUSION

For the reasons and under the arguments and authorities presented above, Applicants respectfully request that the Office's rejection of the pending claims on asserted grounds of obviousness under 35 U.S.C. §103(a) be REVERSED.

Respectfully submitted,

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CLAIMS APPENDIX

1. A disposable article to be fitted to a wearer comprising:
a biosensor including at least one biologically reactive bio-recognition element comprising a biologically derived material and adapted to detect or interact selectively with a specific microorganism selected from the group consisting of pathogenic bacteria, colonic bacteria, viruses, parasites and fungi, present in bodily waste or on the wearer's skin, the biosensor also being adapted to provide a signal of detection of the specific microorganism.

2. (Canceled)

3. The disposable article of Claim 1 wherein the biosensor is selected from the group of: a biocatalytic biosensor and a bioaffinity biosensor.

4. The disposable article of Claim 3 wherein the bioaffinity biosensor is selected from the group of: a chemoreceptor-based biosensor and an immunosensor.

5. The disposable article of Claim 1 wherein the bio-recognition element is selected from the list including: an enzyme or sequence of enzymes; an antibody; DNA; an organelle; a membrane receptor protein; a natural or synthetic cell membrane; viable or nonviable bacterial, plant, or animal cells; at least a portion of a nerve bundle; at least a portion of a sensing organ.

6. The disposable absorbent article of Claim 5 wherein the bio-recognition element is selected from the group including *Acinetobacter baumannii* TOI36 and *Bacillus sp* TOI41.

7. The disposable absorbent article of Claim 6 wherein the bio-recognition element is disposed on a substrate selected from the group of: polymer based materials, hydrogels, tissues, nonwoven materials, and woven materials.

8. (Canceled)

9. The disposable article of Claim 1 wherein the specific microorganism is selected from the group consisting of rotavirus, rhinovirus, human immunodeficiency virus, a parasite, and a pathogenic bacteria selected from the list: *Escherichia coli; Salmonella typhi*; *Salmonella paratyphi*; *Salmonella enteriditis; Salmonella typhimurium*; *Salmonella heidelberg*; *Shigella sonnei*; *Shigella flexneri*; *Shigella boydii*; *Shigella dysenteriae*; *Vibrio cholerae*; *Mycobacterium tuberculosis*; *Yersinia enterocolitica*; *Aeromonas hydrophila*; *Plesiomonas shigelloides*; *Campylobacter jejuni*; *Campylobacter coli*; *Bacteroides fragilis*; *Clostridia septicum, Clostridia perfringens, Clostridia botulinum*, and *Clostridia difficile*.

10. The disposable article of Claim 1 wherein the biosensor detects a target biological analyte associated with a systemic or skin health condition in the wearer prior to the onset of clinically observable symptoms of the condition.

11. The disposable article of Claim 1 wherein the biosensor detects a target biological analyte only above a pre-defined threshold level.

12.-14. (Canceled)

15. The disposable article of Claim 1 wherein the biosensor provides a signal to at least one of the group of: the wearer, a caretaker, an actuator.

16. The disposable article of Claim 15 wherein the signal is a visible indication.

17. The disposable article of Claim 15 wherein the signal is qualitative.

18. The disposable article of Claim 15 wherein the signal is quantitative.

19. The disposable article of Claim 15 wherein the signal is durable throughout at least the usage life of the article.

20. The disposable article of Claim 1 wherein the article additionally comprises a cleaning element for the biosensor.

21. The disposable article of Claim 1 wherein the biosensor is affixed to a support element.

22. The disposable article of Claim 1 wherein the support element adheres to the wearer's skin.

23. The disposable article of Claim 21 wherein the support element is an adhesive tape.

24. The disposable article of Claim 1 wherein the biosensor is detachable from the article.

25. The disposable article of Claim 1 wherein the biosensor adheres to the wearer's skin.

26. The disposable article of Claim 1 wherein the bodily waste is feces, urine or menses.

27. The disposable article of Claim 1 wherein the bodily waste is residual fecal contamination located on the wearer's skin.

28. The disposable article of Claim 1 further comprising an actuator that performs a responsive function when the biosensor detects a target biological analyte.

29. The disposable article of Claim 28 wherein the responsive function is a signal to a caretaker, or the wearer.

30. The disposable article of Claim 28 wherein the actuator transforms a potential energy to perform the responsive function, the potential energy being one or more selected from the group of: mechanical energy, electrical energy and chemical energy.

31. The disposable article of Claim 28 wherein the responsive function is one or more selected from the group of: creating a void volume, treating skin, creating a foaming system and signaling a caregiver.

32. The disposable article of Claim 1 further comprising a receiver.

33. The disposable article of Claim 32 wherein the receiver is integral with said article.

34. The disposable article of Claim 32 further comprising a transmitter.

35. The disposable article of claim 34 wherein the transmitter comprises an infrared telemetry transmitter.

36. The disposable article of Claim 1 wherein the biosensor has a Response Factor of at least 5 when exposed to feces.

37. The disposable article of Claim 1 wherein the biosensor has a Response Factor of at least 10 when exposed to feces.

38. The disposable article of Claim 1 wherein the biosensor has a Response Factor of at least 20 when exposed to feces.

39. The disposable absorbent article of Claim 1 wherein the biosensor has a Response Factor of at least 5 when exposed to a solution of skatole in physiological saline solution having a concentration of 180 micrograms of skatole per gram of physiological saline solution.

40. A disposable absorbent article to be fitted to a wearer comprising:
a topsheet;
a backsheet joined with the topsheet;
an absorbent core disposed between the topsheet and the backsheet; and
a biosensor disposed on the disposable article, the biosensor including at least one biologically reactive bio-recognition element comprising a biologically derived material and adapted to detect or interact selectively with a specific microorganism selected from the group consisting of pathogenic bacteria, colonic bacteria, viruses, parasites and fungi, present in bodily waste, the biosensor also being adapted to provide a signal of detection of the specific microorganism.

41. The disposable absorbent article of Claim 40 wherein the disposable article is chosen from the following group: a sanitary napkin, a diaper, a training pant and an adult incontinence device.

42. (Canceled)

43. The disposable absorbent article of Claim 40 wherein the biosensor is selected from the group of: a biocatalytic biosensor and a bioaffinity biosensor.

44. The disposable absorbent article of Claim 43 wherein the bioaffinity biosensor is selected from the group of: a chemoreceptor-based biosensor and an immunosensor.

45. The disposable absorbent article of Claim 40 wherein the bio-recognition element is selected from the list including: an enzyme or sequence of enzymes; an antibody; DNA; an organelle; a membrane receptor protein; a natural or synthetic cell membrane; viable or nonviable bacterial, plant, or animal cells; at least a portion of a nerve bundle; at least a portion of a sensing organ.

46. (Canceled)

47. The disposable absorbent article of Claim 1 wherein the specific microorganism is selected from the group consisting of rotavirus, rhinovirus, human immunodeficiency virus, a parasite, and a pathogenic bacteria selected from the list: *Escherichia coli; Salmonella typhi*; *Salmonella paratyphi*; *Salmonella enteriditis; Salmonella typhimurium*; *Salmonella heidelberg*; *Shigella sonnei*; *Shigella flexneri*; *Shigella boydii*; *Shigella dysenteriae*; *Vibrio cholerae*; *Mycobacterium tuberculosis*; *Yersinia enterocolitica*; *Aeromonas hydrophila*;

Plesiomonas shigelloides; *Campylobacter jejuni*; *Campylobacter coli*; *Bacteroides fragilis*; *Clostridia septicum, Clostridia perfringens*, *Clostridia botulinum*, and *Clostridia difficile*.

48. The disposable absorbent article of Claim 40 wherein the biosensor adheres to the wearer's skin.

49. The disposable absorbent article of Claim 40 wherein the biosensor has a Response Factor of at least 5 when exposed to feces.

50. The disposable absorbent article of Claim 40 wherein the biosensor has a Response Factor of at least 10 when exposed to feces.

51. The disposable absorbent article of Claim 40 wherein the biosensor has a Response Factor of at least 20 when exposed to feces.

52. The disposable absorbent article of Claim 40 wherein the biosensor has a Response Factor of at least 5 when exposed to a solution of skatole in physiological saline solution having a concentration of 180 micrograms of skatole per gram of physiological saline solution.

EVIDENCE APPENDIX

-None-

RELATED PROCEEDINGS INDEX

-No related proceedings have been identified-